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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/420,719	10/20/1999	MARIKO MIYASHITA	10059-308(P2)	3194

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AKIN, GUMP, STRAUSS, HAUER & FELD, L.L.P.
ONE COMMERCE SQUARE
2005 MARKET STREET, SUITE 2200
PHILADELPHIA, PA 19103

EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/03/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/420,719

Applicant(s)

MIYASHITA ET AL.

Examiner

Kartic Padmanabhan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-28 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-26 and 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>14</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Newly submitted claim 27 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 27 requires a biosensor as part of the apparatus, which is a feature not required of the other claims. Therefore, additional searching would be required for this feature.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 27 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 19-26 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. The recitation of “adapted” in line 7 of claim 19 renders the claim vague and indefinite because applicant has not specified the way in which the instrument is adapted for use with the biosensor.

5. The recitation of “capable” in claim 20 renders the claim vague and indefinite. It is unclear, with this terminology, if the claim requires that the catalyst actually convert the interfering substance into a harmless substance or not.

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6. The recitation of "capable" in claims 22-24 renders the claims vague and indefinite for the same reasons as applied to claim 20 above.

7. The recitation of "adapted" in claims 26 and 28 renders the claim vague and indefinite because applicant has not specified the way in which the instrument is adapted for use with the biosensor.

8. The recitation of "capable" in claim 28 renders the claims vague and indefinite for the same reasons as applied to claim 20 above.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 19-23, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosman et al. (US Pat. 5,079,170). Rosman et al. disclose a sample applicator for use in immunoassays. The applicator comprises a tube with a filter matrix at an end thereof. Sample is filtered to remove interferants as it enters the tube, and is again filtered as it is discharged from the tube in the opposite flow direction. The applicator may also comprise a reagent disposed within the permeable filter matrix, wherein the reagent may include buffering salts or enzymes.

11. Claims 19-20, 22, 25-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Kondo et al. (US Pat. 4,270,923). Kondo et al. disclose a kit for the pretreatment of the body fluids comprising a tube packed with a carboxylic acid-type cation exchange resin fiber and a pipe fitted with a rubber suction cap, to which the tube is to be connected at its lower end.

Preferably, the subject fluid is filtered through the fibrous layer, wherein interfering components

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are removed. The sample is introduced to the tube, filtered to remove interferants, and released at the other end of the tube.

12. Claims 19-20, 22, 25-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Khanna et al. (US Pat. 4,654,311). Khanna et al. disclose serum pretreatment wherein serum is passed through a column containing alkylated silica gel to remove assay interferants. The present invention allows separation of digoxin from endogenous proteins present in serum samples to which digoxin is bound. It is inherent that the column has a sample introduction and sample-releasing part, with the filter material disposed therebetween.

13. Claims 19, 22, 25-26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Liu et al. (US Pat. 5,492,834). Liu et al. disclose the pretreatment of body fluids comprising contacting a sample with a size exclusion gel and obtaining an eluant free of the lower molecular weight analytes (interferants). The eluant can then be assayed for the analyte of interest.

14. Claims 19-20, 25-26, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Blatt et al. (US Pat. 5,945,345). Blatt et al. disclose a device for removing interferants comprising a filter including a solid phase support and an active chemical component for binding the interferant. In one embodiment, a sample is introduced to a solid phase support where the interfering substance is immobilized, and the "clean" sample is released.

15. Claims 19-26 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Obata et al. (US Pat. 5,571,419). Obata et al. disclose a method and apparatus for producing pure water. According to the reference, raw water is introduced into filtration units through a pipe and treated. After undergoing cation exchange, the water ^{is} supplied to an acidic softened water tank and stored. It is inherent that the pH of the raw water is altered in some way in this tank.

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An oxidizing agent, which may be hydrogen peroxide, is added to the raw water through a pipe. A heater provided with a boiler then heats the water. The water is then introduced into a reaction chamber where urea is decomposed by catalytic heat treatment. At the end of the process, the now pure water is released (col. 4, lines 30-67 and Figs. 1-8). Since well water and tap^{water} can be filtered using the apparatus of the reference, it is inherent that the purified water is fit for human consumption in some fashion. Since a person tasting water is interpreted as a biosensor analyzing a sample, the claim limitations are met.

Response to Arguments

16. Applicant's arguments filed June 19, 2001 have been fully considered and are sufficient to overcome the 112 rejections of the previous action and the 102 rejections over Bockowski (US Pat. 5,271,819), Yasuda et al. (US Pat. 5,492,834), and Barden et al. (US Pat. 4,279,618).

However, they are not convincing to overcome the remaining 102 rejections presented in this office action, and applicant's amendments have necessitated new rejections under 35 USC 112.

17. In response to applicant's argument that the cited references do not teach the analysis by a biosensor that electrochemically measures a specific component, it is noted that this recitation is merely the intended use of the sample after treatment. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since intended use is not given patentable weight, claim 26, which only recites

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the intended use of the sample solution after treatment, is not viewed as further limiting the parent claims.

Conclusion

Claims 19-26 and 28 are rejected.

References: Ikeda et al. Yager, and Phelan are cited as art of interest for teaching various pre-treatment and analysis devices.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the


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organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641

March 29, 2002


BAO-THUY L. NGUYEN
PRIMARY EXAMINER
4/1/02